DDM

Display Date 1-15-04

Publication Date 1-16-04

Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of New Animal Drug Application; Ceftiofur

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The supplemental NADA provided revised susceptibility information for food-animal pathogens listed in the clinical microbiology section of labeling for ceftiofur hydrochloride injectable suspension.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail *jgotthar@cvm.fda.gov.*

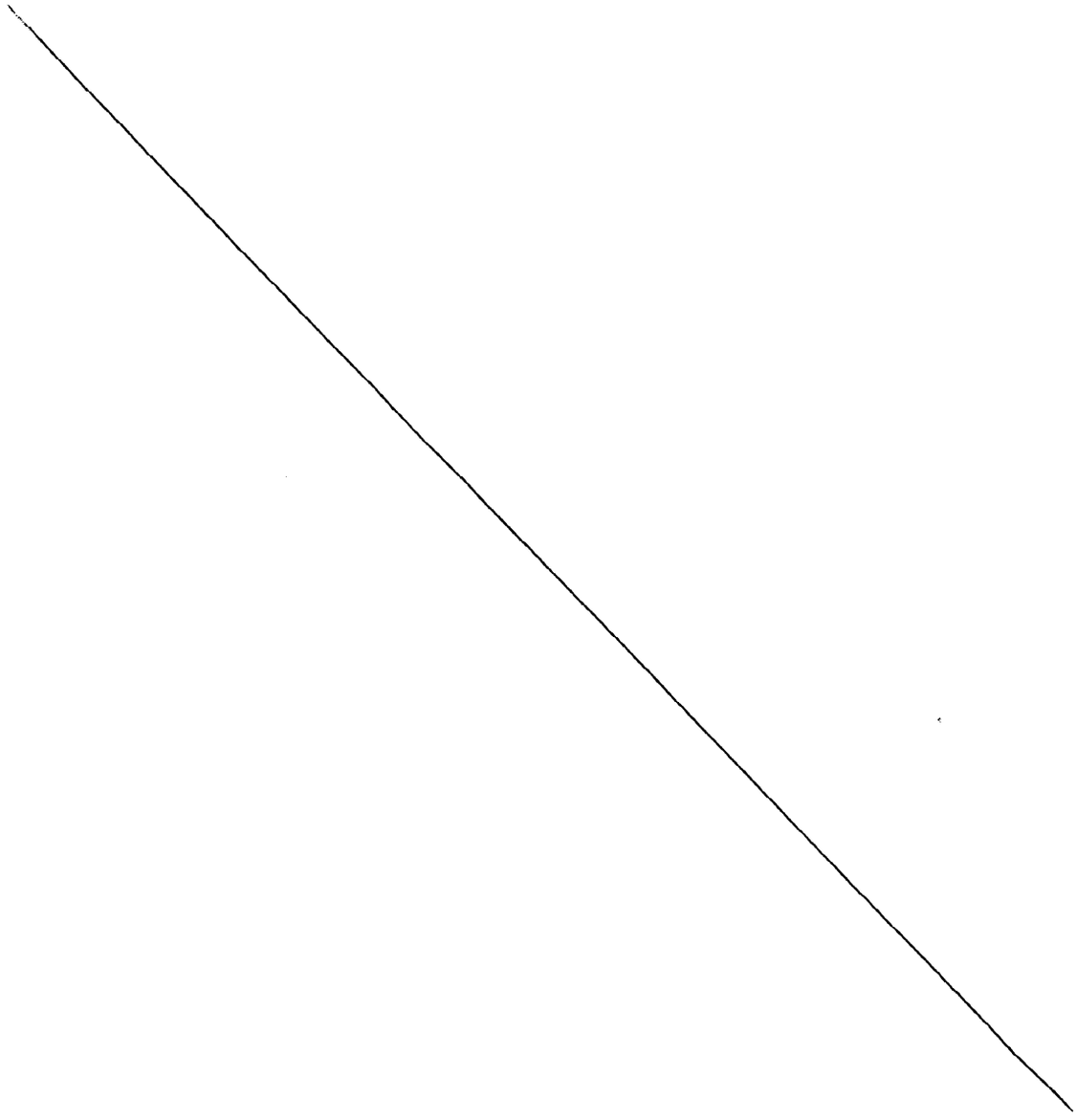
SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed a supplement to NADA 140–890 which provides for the veterinary prescription use of EXCENEL (ceftiofur hydrochloride) RTU Sterile Suspension. The supplemental NADA provided updated susceptibility data for food-animal pathogens listed in the clinical microbiology section of labeling. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that this supplemental NADA is approved as of December 12, 2003. The basis of approval is discussed in the freedom of information summary.

cv03117

NADA 140-890

N 1

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.



The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 31, 2003

December 31, 2003.

Steven D. Vaughn

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S

Dawn P. Hawkins